UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC, et al.,	
Plaintiffs,	Civil Action No. 11-6936 (SRC)
v.	**OPINION & ORDER**
TEVA PHARMACEUTICALS USA, INC.,	
Defendant.	

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for entry of an injunction or stay pending appeal by Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC (collectively, "Plaintiffs") against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"). This Court held oral argument on this motion on March 25, 2015. For the reasons stated below, the motion will be denied.

This case arises from a patent infringement dispute involving a pharmaceutical, Atelvia ®. Plaintiffs own U.S. Patent Nos. 7,645,459 and 7,645,460; Atelvia ® is the product protected by these patents. Teva filed an ANDA seeking to market a generic version of Atelvia®. This case was filed in 2011, and it proceeded to a bench trial before Judge Hochberg of this Court. On March 4, 2015, the Court filed an Opinion and Order, ruling that the two applicable patent claims were invalid for obviousness, pursuant to 35 U.S.C. § 103. The following day, Plaintiffs filed the instant motion, seeking to enjoin Teva from marketing generic Atelvia® during the pendency of an anticipated appeal of the judgment of invalidity to the United States Court of Appeals for the

Federal Circuit.

When deciding a motion for an injunction or stay pending appeal, the Federal Circuit applies the familiar preliminary injunction standard:

> A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.

Winter v. NRDC, Inc., 129 S. Ct. 365, 374 (2008). "These traditional four factors apply with equal force to disputes arising under the Patent Act." Apple Inc. v. Samsung Elecs. Co., 695 F.3d 1370, 1374 (Fed. Cir. 2012) (quoting eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).)

Plaintiffs have failed to demonstrate that they are likely to suffer irreparable harm in the absence of an injunction. There is no dispute that Teva intends to launch its generic version of Atelvia® as soon as it receives FDA permission to do so, and that this could occur at any time.

In many Hatch-Waxman cases like this one, the branded manufacturer argues irreparable injury stemming from the effect of a generic launch on preferred formulary tier status. See, e.g., Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1382 (Fed. Cir. 2006). This case is different. Here, counsel for Teva asserted at oral argument – and Plaintiffs did not contest this – that Atelvia® currently does not have any preferred status in 70% of formularies nationwide.[1] It thus appears that, in most cases, Atelvia® does not have a preferred status to lose from a generic

[1] Teva also offered the declaration of Dr. Bell, who stated that Atelvia® presently has a non-preferred placement in the formularies of 90% of the top ten largest U.S. health insurers, and 65% of the top twenty. (Bell. Decl. Ex. B.) One of Plaintiffs' experts, Dr. Navarro, states that Atelvia® has preferred tier status in 32.5% of formularies, which is not much different from Teva's 70% non-preferred figure. (Supp. Navarro Dec. ¶ 7(d).)

launch. Furthermore, this shows that this is not a case in which a branded pharmaceutical is the market leader in danger of losing its privileged position; to the contrary, Atelvia® is a lesser player in the bisphosphonate market. This substantially lowers the likelihood of irreparable injury stemming from the launch of generic Atelvia®, because Atelvia® is already competing against generics, such as generic risedronate sodium, as well as other generic bisphosphonates. (See Bell Dec. ¶ 10.)

Moreover, Plaintiffs state that revenues from Atelvia® are expected to be stable, absent a generic launch, making it a relatively simple matter to estimate lost revenues due to the launch of a generic version, and thus to calculate money damages. (Cukier Dec. ¶ 11.) There do not appear to be any special circumstances here that will make the quantification of lost profits especially difficult. Should the judgment of invalidity be reversed on appeal, Plaintiffs' lost revenues will be readily compensable by money damages.

Plaintiffs' arguments about irreparably injurious impacts of other kinds is speculative and unsupported. Plaintiffs contend that they will also be irreparably harmed by a generic launch because it will "place jobs at risk." (Pls.' Br. 7.) Plaintiffs openly state, however, that the 145 employees on the Atelvia® sales force spend only 10% of their time on Atelvia®. (Id.) This indicates that a generic launch is likely to have a very small impact on the Atelvia® sales force.

Plaintiffs also contend that they will be irreparably harmed by a generic launch because it will detrimentally affect their funding for research and development. (Pls.' Br. 8.) There is no dispute that Warner Chilcott is a wholly-owned subsidiary of Actavis. Teva points to the fact that Actavis' 2014 10-K statement reports that the company, as a whole, spent over a billion dollars last year on research and development. (Def.'s Opp. Br. at 10, citing Actavis 2014 10-K

at 72.) Plaintiffs state that they forecast roughly $50 million in sales from Atelvia® in 2015. (Pls.' Br. 6.) The impact of the conceivable loss of revenue from a launch of generic Atelvia®, on a billion dollar research budget, is tiny. This Court is not persuaded that these other kinds of impacts adequately support a finding of irreparable injury.

The balance of equities certainly tips in favor of Teva: after years of litigation, Teva won a judgment in its favor at trial. Staying a hard-won judgment can hardly be viewed as equitable. "The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." Univ. of Tex. v. Camenisch, 451 U.S. 390, 395 (1981). Here, a trial on the merits *has* been held. The traditional purpose of preserving the *status quo* pending trial is inapplicable here.

This Court finds that Plaintiffs have failed to show that they are likely to suffer irreparable harm in the absence of preliminary relief, nor that the balance of equities tips in their favor. "[A] trial court may . . . deny a [preliminary injunction] motion based on a patentee's failure to show any one of the four factors--especially either of the first two--without analyzing the others . . ." Guttman, Inc. v. Kopykake Enters., 302 F.3d 1352, 1356 (Fed. Cir. 2002). Plaintiffs have failed to meet the requirements for a grant of injunctive relief. Plaintiffs' motion for an injunction pending appeal will be denied.

Plaintiffs ask, in the alternative, that this Court enjoin Teva from launching a generic version of Atelvia® for ten days to allow Plaintiffs to move before the Federal Circuit for an injunction pending appeal of this Court's Final Judgment. This is entirely reasonable, and the request for a temporary injunction will be granted.

For these reasons,

IT IS on this 30th day of March, 2015 hereby

ORDERED that Plaintiffs' motion for an injunction pending appeal (Docket Entry No. 308) is **DENIED**; and it is further

ORDERED that Teva is hereby temporarily **ENJOINED** from launching a generic version of Atelvia® for 10 business days from the date of entry of this Order to provide an opportunity for Plaintiffs to move before the Federal Circuit for an injunction pending appeal of this Court's Final Judgment.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.